

**Frequently Asked Questions (FAQs)**  
about  
**The California Department of Health Care Services**  
**Medi-Cal Program Enteral Nutrition Products Contracting Process**

**CONTRACTING OVERVIEW**

The following **FAQs** address the contracting process that results in a "List" of contracted enteral nutrition products. The companion document to this is the more detailed "Enteral Nutrition Products Review Procedures".

The Department hosts a periodic **Product Category Review (PCR)** that results in policy decisions to create a "List of Contracted Products" published in the Medi-Cal Provider Manual as a potential benefit of the program. Once listed products undergo Prior Authorization via the Treatment Authorization Request (TAR) process, as in the past.

The contracting process is not a formal government bid process, but a negotiation process, provided for in statute (*Welfare and Institutions Code, Section 14105.8*). The process begins with evaluation of products for 5 criteria and ends with a List of products made by one or more manufacturers, each with a contracted Maximum Acquisition Cost (MAC).

The steps for a contractor to apply for the placement of a product on the "List" include a presentation of products to Medi-Cal and its volunteer Nutrition Advisory Committee (in person or by correspondence), followed by a decision to proceed with contracting for medically necessary items only (items that protect a patient from injury or death; see the "Enteral Nutrition Products Review Procedures" document for details). The presentation is required for all products to discern household items (non-benefits by law), experimental items, and investigational items that may not be deemed medically efficacious and necessary without presentation of clinical evidence.

Next, the Department invites a business (price) proposal from the company wishing to add products to the "List", and price negotiations begin. When the Department feels there is access to enough products for the fee for service outpatient population, at a reasonable price, the Department issues all companies a last and final offer for efficacious products. Companies can at that time agree to contract for all proposed items, or eliminate some proposed products, or entirely self-eliminate from the process. Only products contracted are placed on the "List", and all other products are non-benefits on the implementation date that follows a transition period for pharmacy providers to exhaust old stock.

**GENERAL CONTRACTING FAQs**

**Q1: Who are the beneficiaries of the products in this contracting process?**

*The contracting process is for the creation of a "List" of products as potential benefits of the Fee-For-Service outpatient population in California's Medicaid (Medi-Cal) Program (approximately 3.2million beneficiaries). This population also includes California Childrens' Services program and Genetically Handicapped Persons program Medi-Cal beneficiaries. Placement on the List is not a guarantee that the product will be approved and paid every time.*

*Managed Care Medi-Cal patients are not directly affected by the creation of this "List" since managed care organizations carry out Medicaid rules in their own unique contract with the Department and using their own unique business model and benefit package approach. They can however, choose to adopt the contracted List.*

**Q2: Who can contract with Medi-Cal for Enteral Nutrition Products?**

*Companies eligible to enter an agreement with the Department, for placement of products on the List must be either (a) the manufacturer of the product or (b) a relabeler, or repackager, with a unique labeler code. The products subject to review must be available for purchase by any Medi-Cal pharmacy providers who dispense to eligible outpatients in California.*

**Q3: Is there a list of pharmacy providers who dispense nutrition products available?**

*No. Medi-Cal does not publish a list of providers. Your product category review manager can provide you with a list of past paid claims for your product, by provider, upon request.*

**Q4: Can the Department guarantee a volume of business to the Contractor?**

*No.*

**Q5: Why are products judged for medical necessity?**

*Medi-Cal is a medical treatment program with benefits intended for use by patients (beneficiaries) for the direct health benefit of those patients, vs. caregivers or the environment. Products are judged using five criteria outlined in the "Enteral Nutrition Products Review Procedures" document.*

**Q6: Who judges the medical necessity of products?**

*The Medi-Cal Pharmacy Policy and Contracting Unit uses the input of health care professionals and analysts who evaluate the five criteria for placement of a product on the "List". The team uses literature review provided by product manufacturers/ distributors/clinical experts and invites outside experts to provide input into the evidence based policy decision process.*

**Q7: Can I get a copy of the contract we will need to sign with the Department?**

*Ask the project manager in charge of your product review for a copy of our boilerplate contracts. It is important to have your company review our boilerplate contract language ahead of time so that if your product is added to the "List", the boilerplate contract can be signed quickly.*

**Q8: Can the contract language be changed?**

*No. The contract is a Department of Health Care Services, Office of Legal Services-approved document and cannot be changed for any reason.*

**Q9: What aspects of the contract negotiation process are confidential?**

*Confidentiality requirements are applicable to the Product Category Review (PCR) AND the Petition processes described in this document. Confidentiality is required of all participants engaged in the contracting process. All conflict of interest, and anti-trust and collusion laws must be strictly adhered to by all. This includes, but is not limited to:*

*§ active promotion of products proposed for addition to the "List" shall not occur until the provider bulletin is published; AND*

*§ prices proposed to the Department, counter offers from the Department, and final contracted prices shall not be shared or announced until the provider bulletin is published; REBATES ARE NEVER PUBLIC INFORMATION AND REMAIN CONFIDENTIAL; AND*

*§ Failure to comply with confidentiality requirements may result in a delay of the addition of products to the "List", or cancellation of a contract.*

**Q10: How do I know which products are already on the "List"? Where can I learn about the other aspects of the Pharmacy Program?**

*The "List" is published in our Pharmacy Provider and Allied Health Provider Manuals. The easiest way to see the "List" is to go to the Department's web site, [www.medi-cal.ca.gov](http://www.medi-cal.ca.gov). Click on Provider Manual, "Pharmacy", and on the next page click on "Part 2-Pharmacy" for enteral nutrition products information. Other Program Manuals are also available on this site. The Provider Manuals are the most comprehensive reference on the Medi-Cal pharmacy program, and contain answers to many questions.*

**Q11: I have more questions. Where can I get answers?**

*Call the project manager assigned to review your product. He or she can answer your questions. You are encouraged you to carefully read the "Enteral Nutrition Products Review Procedures" document, which explains many of these points in much greater detail than given here. If you don't have a copy of that document, please request a copy from your assigned project manager.*

## **BUSINESS & FINANCIAL CONTRACTING FAQs**

**Q1: If the volume of business a Contractor experiences from Medi-Cal beneficiaries does not turn out to be adequate to justify a "best" price, can the Contractor abandon the contract?**

*Yes, there is a 90 day 'out clause' in the contract.*

**Q2: Why are the products that end up on the "List" only potential benefits, and not guaranteed benefits?**

*All enteral nutrition products require prior authorization (the approval of a Treatment Authorization Request (TAR) if straight Medi-Cal, or Service Authorization Request, (SAR), if CCS/Medi-Cal. For example, enteral nutrition products are approved via the prior authorization process on a patient by patient basis. Product placement on the "List" of contracted products does not guarantee approval via prior authorization in every case where a product is prescribed. Product placement on the "List" only makes the product available for consideration via prior authorization.*

**Q3: If my company does not have contracts with its distributors and wholesalers, how can I guarantee the MAC and other conditions of this contract are honored?**

*The intent of the contract is to allow the provider to purchase the contracted product at or below the MAC price. The DHCS does not dictate how this is accomplished, only that a mechanism exists. It is the Contractor's responsibility to determine a reasonable mechanism by which to meet the intent of the agreement.*

**Q4: How are Providers paid by the Department?**

*California Code of Regulations (Title 22, Section 51513(a)(6)) defines payment to providers based on the Estimated Acquisition Cost (EAC) plus a markup. EAC is determined by the Department.*

*Example:*

*§ EAC for enteral nutrition products can be Average Wholesale Price (AWP) minus 10%, invoice price, catalog price, or a contracted price;*

*On implementation of a MAC contract, the MAC becomes the EAC for the contracted enteral nutrition product.*

**Q5: Will the % markup change after contracts are in place?**

*No. the % markup is defined in law and is not part of this negotiation process.*

**Q6: How can I get data on the Department utilization of our product, and of our competitor's products?**

*Please contact the project manager assigned to your review.*

*§ For products with product numbers converted to NDC-like format, and paid through the pharmacy payment system (as with enteral nutrition products) you can download monthly and quarterly reports of fee-for-service pharmacy utilization, by NDC on our web site, free of charge. Go to [www.dhcs.ca.gov/mcs/mcpd/MBB/contracting/files](http://www.dhcs.ca.gov/mcs/mcpd/MBB/contracting/files)*

*§ The Department publishes monthly, quarterly, and annual reports of fee-for-service pharmacy utilization, in NDC order. These are available for public viewing at the California State Library Government Publications Section, which is currently located at:*

914 Capitol Mall, Fourth Floor  
Sacramento, CA 95814  
Phone: 916-654-0069

§ The Department's Medical Care Statistics Section can assist you in obtaining more detailed data, and analysis, for a fee. On the Internet, go to [www.dhcs.ca.gov/mcss](http://www.dhcs.ca.gov/mcss) for more information. If you can't find what you need on the website contact Jim Watkins, Chief of the Medical Care Statistics Section at [jim.watkins@dhcs.ca.gov](mailto:jim.watkins@dhcs.ca.gov)

**Q7: I have more questions. Where can I get answers?**

*Call the project manager assigned to review your product. He or she can answer your questions.*

*You are encouraged you to carefully read the "Enteral Nutrition Products Review Procedures" document, which explains many of these points in much greater detail than given here. If you don't have a copy of that document, please request a copy from your assigned project manager.*

## **PRESENTATION FAQs**

### **Q1: Why is a presentation required?**

*Medi-Cal requires all companies that make enteral nutrition products proposed for addition to the List be present, in person, for a presentation of the five criteria in order to establish relationships and assure established companies and products are placed on the List, for the beneficiary population. Products without a current retail presence are not considered for contracting.*

### **Q2: What should we talk about in the presentation?**

*The Department will evaluate your product using five criteria - Safety, Efficacy, Essential Need, Misuse Potential, and Cost. Company representatives attending the meeting should address these criteria, e.g., what makes this product more safe or effective than other products the Department has, or is considering for its "List"? Why does the Department need this product if other similar product are already on the "List"? What are the chances that prescribers will misuse this product (i.e., prescribe this product when equally efficacious less expensive products are available or appropriate)? What makes this product cost-effective to the Department? We discuss the Cost criterion in more detail later in this document.*

*With regard to the Cost criterion, you should make a business proposal that addresses the cost of the item to the Department.*

### **Q3: What information should appear in the business proposal?**

*For each product in question, companies should propose to the Department the Product Name of the item, Product Number, the package size (if applicable), flavor, form, and all of the details of the price proposal (Maximum Acquisition Cost). Example:*

<i>Product Number</i>	<i>Product Name</i>	<i>Package Size</i>	<i>Proposed <u>MAC</u> per unit of product</i>
12345678910	XYZ liquid	240 ml	0.00450
12345678911	ABC liquid	1500 ml	0.00570

### **Q4: How long is the presentation meeting?**

*Typically we schedule the meeting room for one and one-half to two hours. This leaves time for a one-hour or more presentation, plus questions. There generally will not be an opportunity for a second meeting, so budget your time carefully.*

### **Q5: Does the Department provide audio-visual equipment?**

*No, there is no audio-visual equipment available. Meeting rooms have electrical outlets only. You must provide your own projectors, laptops, extension cords, etc.*

### **Q6: Who will attend from the Department and elsewhere?**

*The project manager who has been assigned to your product will attend, along with other health care professionals and analysts that make up the committee that evaluates the five criteria for placement of a product on the "List". Staff from other programs may also attend (California Children's Services and the Genetically Handicapped Persons Program; the Women Infants and Childrens Supplemental Food Program; Maternal, Child, and Adolescent Health; Medi-Cal Managed Care; etc.) Members of the Nutrition Advisory Committee (NAC) made up of experts in*

*private practice and local level government programs with experience in the patient and diagnosis for the Product Category, will also attend in person and by conference call. If you have handouts for your presentation PLEASE send them in electronically, at least one week ahead of the presentation so that the project manager can assure everyone on conference call-in have ample time to receive your handouts in advance. Please bring enough copies for all members attending in person by asking the project manager how many are expected.*

**Q7: What should we bring to our meeting?**

*Be prepared to address the Five Criteria. **Address the first Four Criteria to the entire audience.** Address the Cost criteria to Medi-Cal **only** by sharing your MAC pricing proposal with the project manager only. Bring a written business proposal that includes all cost information for the contract. Bring samples of the product for visual aids to support the content of your presentation. Bring examples of your direct-to-consumer marketing materials.*

**Q8: Whom should we bring to the meeting?**

*Most of our meeting rooms hold ten to thirty people. The Department assigns four to five persons to attend, and the NAC includes up to 10 attendees, leaving five or more persons that the Contractor can bring. It has been our experience that bringing more people than this does little to enhance the presentation. Please be sure to tell the project manager assigned your product the names of individuals you plan to bring, in advance, so that we can schedule an appropriately sized room, and notify our security desk of your arrival.*

*Emphasis should be placed on sending your company's CLINICAL experts, since the medical necessity, safety, and overall clinical importance of the product must be established before cost and other considerations can be addressed. Some Contractors send the product manager, attorneys, local, regional and national sales managers, and financial experts. Others send only one or two people as spokespersons. You should emphasize one or two medical experts on the product who can discuss the product from a prescriber's medical use perspective.*

**Q10: What happens after the meeting?**

*The project manager assigned to the product category and other Medi-Cal policy staff will meet with the NAC members to receive the Committee's recommendations to cover or not cover a given list of items based on the five criteria. The project manager will next meet with the Department to make recommendations consistent with the Centers for Medicare and Medicaid-approved State Budget and State Plan, Title 22, and statutory requirements in California.*

*If the Department has additional questions, the project manager will contact contractors for more information. A decision will then be made. The choices typically are to add the product as proposed, or to reject the petition, or to make a counter price proposal. Reminder: this is a contract negotiation process that can result in one or more Contractors' products appearing on the "List". This is not a competitive bid process.*

*Counter-proposals usually involve a change in the proposed price, and sometimes a proposed "Code 1" restriction of some type, such as limiting the product's use to patients with a certain diagnosis, a certain age, health status, etc. The counter-proposal is usually made by . The Department generally gives the Contractor a specified length of time to respond to counter-proposals.*

*Project managers will develop an ongoing review process schedule. You may call the project manager assigned to your product periodically to check on the status of your product review.*

**Q11: I have more questions. Where can I get answers?**

*Call the project manager assigned to review your product. He or she can answer your questions.*

*The "Enteral Nutrition Products Review Procedures" document explains many of these points in much greater detail than given here. If you don't have a copy of that document, please request a copy from your assigned project manager.*



## **MAC CONTRACTING FAQs**

### **Q1: What is a Maximum Acquisition Cost contract?**

*A Maximum Acquisition Cost (MAC) contract guarantees an acquisition cost as the maximum selling price to all providers for use only with their Medi-Cal beneficiaries. The MAC sets only the purchase, or acquisition cost, for the provider. The MAC will be used as a basis for determining the provider reimbursement rate. Providers may be reimbursed the contracted price (MAC) plus a markup, or the provider's actual net cost plus a markup, whichever is less.*

### **Q2: How does the Department view the fifth criterion, cost, in a MAC contract?**

*Cost effectiveness means the immediate or long-term cost effectiveness of the product. Evaluation of cost effectiveness may involve a single enteral nutrition product or comparisons between two or more enteral nutrition products. This may take into account such factors as the actual cost of the product to the Department, plus any fiscal impact resulting from improvements in emergency room use, acute facility use, the time for the medical condition to achieve resolution, and/or the reduced utilization of ancillary therapeutic agents.*

*And, the Department views actual cost as follows:*

<i>IF:</i>	<i>THEN:</i>
<i>The contracted MAC is \$0.04500 per ml or gm of product,</i>	<i>The cost to the Department is \$0.04500x1.23 (*23%markup to the provider), =\$0.00553 per ml or gm of product</i>

### **Q3: How and when will the Contractor know whether providers are entitled to the MAC price for dispensing only to Medi-Cal patients?**

*The Department recommends Contractors take necessary precautions to ensure provider utilization and entitlement to the MAC is appropriate. Data is available for purchase from several private companies that currently offer utilization information to drug companies for similar purpose. The same data is currently available for enteral nutrition products because they are mingled in Medi-Cal's drug utilization data.*

*On request the Department can provide provider-level detail of product payments that represent the paid claims for one quarter. Providers have 6 months in which to turn in all claims for the dispensing in a quarter.*

### **Q4: I have more questions. Where can I get answers?**

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